UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

TRACK 1 DEFENDANTS'
MEMORANDUM IN SUPPORT OF MOTION TO STRIKE
THE DECLARATION OF RAYMOND S. HARTMAN

The Track 1 defendants (hereinafter "defendants")[1] submit this memorandum in support of their motion to strike the expert declaration of Dr. Raymond S. Hartman ("Hartman Decl."), submitted by plaintiffs in support of their motion for class certification.

Hartman's declaration is aimed at shoring up the radical shift in plaintiffs' theory of the case. Plaintiffs survived two motions to dismiss by persuading the Court that AWP literally means an average of actual acquisition costs. Recognizing that definition never had any support in the real world, plaintiffs now proffer Hartman, who concedes that AWPs exceed acquisition costs in widely varying amounts. Yet Hartman claims to be able to determine class-wide injury and damages by conjuring up a "but-for world" based on payers' "expectations" concerning the spread between AWP and a so-called "average sale price" ("ASP").

Hartman's "expectation" methodology is so patently flawed that his declaration should be stricken. Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), courts have discretion to strike or disregard unreliable expert testimony at the class certification stage. Hartman's methodology is unreliable on its face and fails every test of reliability identified in *Daubert*.

HARTMAN'S METHODOLOGY

Dr. Raymond S. Hartman is an economist. He states that he has been asked to analyze "whether causation, injury and liability can be proven on a class-wide basis." (Hartman Decl. ¶ 7.) He concludes that a "formulaic methodology" can be used to prove these issues on a class-wide basis. (*Id.* ¶¶ 34, 37.)

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[1] The Track 1 defendants are the AstraZeneca Group, the BMS Group, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, the Johnson & Johnson Group and the Schering-Plough Group.

To do so, Hartman first intends to generate an average sale price ("ASP") for each NDC of each drug. (Hartman Decl. ¶¶ 11, 36; Hartman Dep. Tr. 122.)[2] Then, Hartman plans to create a "yardstick" to represent the class's "expectations" with respect to the "spread" between his ASP and AWP. (Hartman Decl. ¶ 31.) The "yardstick" will be used to create a "but-for" AWP which he will compare to the AWPs that were reported during the class period. (*Id.* ¶ 20.) Hartman states: "If the actual spread exceeds the but-for spread, I can conclude that the AWP scheme led to reimbursement in excess of those [sic] reasonably expected by the market." (*Id.*) Stated simply, Hartman will find class-wide liability, injury and damages if he concludes that the actual difference between AWP and his ASP was greater during the class period than the "average" that the class as a whole expected.

Hartman testifies in his declaration that he has generated preliminary "yardsticks" for five categories of drugs.[3] He states that yardsticks can be calculated using "industry-wide survey information" and/or by using "actual AWP and ASP data from those manufacturers and their drugs known to be unaffected by the AWP scheme." (*Id.* ¶ 21; Hartman Dep. Tr. 176-77.) At his deposition, Hartman explained that he plans to determine the market expectations of all third party payers in the putative class by surveying at least two to four large institutions, three to five mid-sized entities (perhaps differentiated by type of payer), and five to seven small third party payers. (Hartman Dep. Tr. 348-49.) Hartman then plans to average together these surveyed

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[2] Hartman says he will determine his ASP by determining net revenue (after taking into account all rebates, discounts and other "price offsets"), and dividing that figure by the number of units sold. (Hartman Dep. Tr. 460-65.) We discuss the flaws in Hartman's way of determining and applying his ASP in Section II.B below. Dr. Hartman's deposition testimony is annexed to the attached Declaration of Halbert L. White, Jr.

[3] They are: (1) single-source drugs reimbursed through pharmacy benefit managers ("PBMs"); (2) multi-source drugs reimbursed through PBMs; (3) physician-administered drugs covered by Medicare Part B; (4) physician-administered drugs reimbursed by private third party payers; and (5) generic drugs sold by retail pharmacies. (Hartman Decl. ¶ 33.)

class members' individual expectations to calculate "aggregate impacts" for the entire class. (*Id.* at 359.) Hartman is not concerned about variations in the actual expectations among different putative class members, because he believes his yardsticks will capture "the average of the market understanding of the difference between AWP, WAC, and ASP". (*Id.* at 373.)

Hartman has not talked to any class members, PBMs, manufacturers, pharmacies, wholesalers or physicians in developing his methodology. (Hartman Dep. Tr. 88, 333-34.) He has not relied on any of the depositions in the case, other than the deposition of one class member. (*Id.* at 27-28, 91-92, 231.) Although Hartman's report suggests that participants in his survey will have similar understandings, he stated at his deposition that this was a "guess" on his part. (*Id.* at 352.)

Hartman was unable to identify any authority for the proposition that "but-for" expectations can be determined by conducting surveys and calculating averages. (Hartman Dep. Tr. 52-53, 260-61, 338-340.) He acknowledged at his deposition that the many articles and other sources cited in his declaration as support for his approach do not discuss his methodology. (*Id.* at 47-53.)

Hartman does not deny that his methodology was created for purposes of this litigation. (Hartman Dep. Tr. 54-55.) Indeed, he appears to be the "go-to" litigation economist for plaintiffs' counsel; Hartman testified that he has worked on five to ten projects for plaintiffs' counsel for which he may have received as much as $5 million in the last five years. (*Id.* at 58-60.) Hartman has never submitted a report concluding that a class should not be certified or that injury could not be determined on a class-wide basis. (*Id.* at 37.) He testified that while there may be putative classes that should not be certified, "I haven't seen one." (*Id.* at 38.)

ARGUMENT

I. Proffered Expert Evidence That Is Unreliable Should Not Be Considered In Support Of A Motion For Class Certification.

"[T]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action." *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 469 (1978) (internal quotation marks omitted). For that reason, district courts must conduct a "rigorous analysis" of plaintiffs' asserted grounds for class certification and "probe behind the pleadings" where necessary to resolve the certification question. *General Telephone Co. v. Falcon*, 457 U.S. 147, 160-61 (1982). Because "[t]he more complex determinations required in Rule 23(b)(3) class actions entail even greater entanglement with the merits," *Coopers & Lybrand*, 437 U.S. at 469 n.12 (internal quotation marks omitted), district courts facing requests for certification under Rule 23(b)(3) must "formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate." *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 298 (1st Cir. 2000); *see Tardiff v. Knox County*, 365 F.3d 1, 4-5 (1st Cir. 2004) (district courts may "test disputed premises early on if and when the class action would be proper on one premise but not another.").

Accordingly, when a plaintiff offers expert testimony in support of a request for class certification, the district court has the responsibility to test the expert's proffered methodology to determine whether it provides a reliable basis on which to certify a class. A court cannot simply defer to a well-credentialed expert at the certification stage and take a hard look later, for "[t]hat amounts to a delegation of judicial power to the plaintiffs, who can obtain class certification just by hiring a competent expert." *West v. Prudential Securities, Inc.*, 282 F.3d 935, 938 (7th Cir. 2002). Thus, when faced with proffered expert testimony,

> [a] district judge may not duck hard questions by observing that each side has some support, or that considerations relevant to class certification also may affect the decision on the merits. Tough questions must be faced and squarely decided, if necessary by holding evidentiary hearings and choosing between competing perspectives.

Id. (reversing class certification where expert's methodology did not provide a reliable basis for proving causation).[4]

The touchstone for testing the reliability of an expert's proffered methodology is *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).[5] "In many cases, it makes sense to consider the admissibility of the testimony of an expert proffered to establish one of the rule 23 elements in the context of a motion to strike prior to considering class certification." *Bell v. Ascendant Solutions, Inc.*, No. CIV.A. 30/CV0166N, 2004 WL 1490009 at *2 (N.D. Tex. July 1, 2004). It is particularly appropriate to use *Daubert* at the certification stage to screen expert testimony that is "inherently unreliable because of the methodology employed." *Yapp v. Union Pac. R.R.* Co., 301 F. Supp. 2d 1030, 1036 (E.D. Mo. 2004); *see also McNamara v. Bre-X*

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[4] Judge Young has suggested that at the certification stage "the Court considers only whether the evidence that the direct purchaser plaintiffs will offer in support of their interpretation will be sufficiently generalized in nature." *In re Relafen Antitrust Litig.*, 218 F.R.D. 337, 344 (D. Mass. 2003) (internal quotation marks and citation omitted). This restrictive approach appears to be inconsistent with the Court of Appeals' subsequent direction that district courts may "test disputed premises early on if and when the class action would be proper on one premise but not another." *Tardiff*, 365 F.3d at 4-5.

[5] In *Daubert*, the Supreme Court articulated the standard that testimony concerning "scientific knowledge" must meet in order to be admissible under Fed. R. Evid. 702. "[T]he word 'knowledge,'" explained the Court, "connotes more than subjective belief or unsupported speculation." 509 U.S. at 590. "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method," a requirement necessary to ensure "evidentiary reliability." *Id.* Accordingly, courts must determine "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. The Supreme Court later explained that this standard applied to non-scientific as well as scientific expert testimony submitted pursuant to Fed. R. Evid. 702. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). The First Circuit has confirmed that "[t]he district court's gatekeeping function extends to all expert evidence, including economic analysis." *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 175 F.3d 18, 34 n.12 (1st Cir. 1999) (citing *Kumho Tire*).

Minerals Ltd., No. 5:97-CV-159, 2002 WL 32076175 (E.D. Tex. Sept. 30, 2002) (concluding that a well-credentialed economist's specific proffered methodology was unreliable under *Daubert* and therefore inadmissible in support of plaintiffs' request for class certification); *Corley v. Entergy Corp.*, 220 F.R.D. 478, 485 (E.D. Tex. 2004) (disregarding proffered expert testimony at the certification stage because proposed class-wide damages methodology did not satisfy *Daubert*); *cf. Sanneman v. Chrysler Corp.*, 191 F.R.D. 441, 451 (E.D. Pa. 2000) (considering expert's testimony at the certification stage because it satisfied *Daubert*).[6]

II. Hartman's Methodology Is Facially Unreliable.

Hartman proposes to determine class-wide causation, injury and liability by generating two numbers and then comparing them.[7] Under Hartman's methodology, if the "actual spread" is larger than the "but-for spread" – that is, if the real spread between AWP and his ASP was larger than the *average* expectation of the class – then Hartman will conclude that liability and injury exist for *all* class members. We show below that Hartman's two "spread" numbers bear no relation to the real world and that Hartman's methodology is so flawed that it is unreliable on its face.

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[6] Even those courts that have applied a "limited" *Daubert* review at the certification stage focus on the reliability of the expert's *methodology*, and leave an assessment of the proffered *conclusions* to another day. *See, e.g., DeMarco v. Lehman Bros., Inc.*, 222 F.R.D. 243, 248 (S.D.N.Y. 2004) (applying limited *Daubert* scrutiny to conclude that expert's proffered methodology was unreliable on its face and could not be considered in support of class certification); *Midwestern Machinery v. Northwest Airlines, Inc.*, 211 F.R.D. 562, 565-66 (D. Minn. 2001) (concluding that "*Daubert* is helpful to the extent that it can assist the Court in preventing the entrance of methodology so apparently flawed," but that the court should not "look beyond the methodology and critique the prospective results of its application to a complete set of data"); *Vickers v. General Motors Corp.*, 204 F.R.D. 476, 479 (D. Kan. 2001) (exercising discretion to reject proffered expert testimony under *Daubert*); *cf. In re Visa Check/Mastermoney Antitrust Litigation*, 280 F.3d 124, 133-35 (2d Cir. 2001) (holding that district court did not abuse its discretion in admitting expert report where lower court thoroughly examined expert's methodology in a forty-plus page opinion). The instant motion is directed at Hartman's methodology rather than his conclusions.

[7] Hartman Dep. Tr. 123-24 ("Q: Your basic approach, as I understand it, is to compare actual spreads to but-for spreads to determine whether there was injury? Is that correct? A: The – briefly put, that is correct.")

A. Hartman's Methodology Is Unreliable Because It Determines Liability And Injury Using An Average Expectation "Yardstick" That Disregards Class Members' Actual Expectations.

1. By defining causation, injury and liability in terms of a class-wide "average" expectation, Hartman's methodology assumes what it sets out to prove.

Hartman conceded in his deposition that knowledge and expectations about the size of the "spread" between AWP and his ASP differed from one class member to next.[8] But Hartman's methodology does not account for these real-world variations in class members' expectations. Instead, Hartman creates a single, average expectation "yardstick" for an entire category of drugs, and then applies that average "yardstick" to every member of the class:

> And I am characterizing a single – a yardstick that characterizes the average of the market understanding of the difference between AWP, WAC, and ASP. So it is him, it is going to be the same – the yardstick is going to be the same for everybody.

(Hartman Dep. Tr. 373.) Critically, Hartman testified that he plans to apply the same average expectation "yardstick" to the thousands or millions of putative class members, *even if class members' actual, real world expectations differ from his "yardstick"*:

> Q: So the answer to my question is yes, you would apply the average yardstick to Mr. Beaderstadt and other class members even though they may have had expectations that were different from the average?
>
> MR. SOBOL: Objection.
>
> A: I'm going to apply the yardstick for the market as a whole to characterize the AWP as a whole to the market as a whole and for everybody: for Mr. Beaderstadt, for Mr. Jones who is the CFO of

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[8] Hartman Dep. Tr. 100 ("And what I'm saying is the extent to which they have knowledge needs to be ascertained, and that will affect the quanta of how they're impacted."); *see also* Hartman Decl. ¶ 10(b) ("some end payers have understood that the AWP is greater than the manufacturer's average sale price (ASP)"). As discussed in defendants' brief in opposition to class certification, the discovery record confirms the wide variation in end payer knowledge and expectations concerning actual or average prices and the size of the "spread."

> CIGNA, and the – each of those – those – those two individuals have – have different knowledge, different abilities to negotiate.

(*Id.*; *see also id.* at 369.)

By consciously disregarding known variations in the expectations of individual putative class members and asserting that liability can be proven using a uniform class-wide expectation "yardstick," Hartman's methodology simply assumes what it sets out to prove. But reaching individual determinations of liability and injury using a single "average expectation" for the entire putative class is no more reliable than distributing individual speeding tickets based on the "average speed" of 1,000 drivers. It would certainly be possible to calculate an "average speed" for those drivers, or to sample a few dozen of those drivers and generate an average. But the fact that that the "average speed" of the 1,000 drivers (or some sample) was higher than the speed limit would not prove that *all* 1,000 drivers were speeding. Yet that is precisely what Hartman proffers here when he proposes to determine liability and injury for every putative class member by selecting as his starting point a uniform average "yardstick" that disregards putative class members' actual expectations.

The consequence is that Hartman will find *class-wide* causation, injury and liability even if some or even many *individual* class members were unaffected by the alleged scheme. Under Hartman's methodology, a putative class member who was not misled would satisfy Hartman's test for injury, causation and damages.[9] So would a class member who believed that AWP had

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[9] Assume the "actual spread" were 50%, and a class member knew (or "expected") the spread was 50%, but the class-wide average "yardstick/but-for spread" was 20%. Because the difference between the "actual spread" (50%) and the class member's "but-for spread" (50%) would be 0%, there would be no liability, injury or damages for that class member if Dr. Hartman's methodology reflected that class member's actual, real world expectations. But because Dr. Hartman's methodology would use the class-wide average "yardstick" instead of the class member's actual expectation, Dr. Hartman would find liability, injury and damages for the very same class member.

no consistent relationship to average or actual sales prices.[10] Under Hartman's faulty logic a class member would be impacted even if its contract with a PBM calls for a discount of 99% below AWP.[11] Similarly, he is not prepared to conclude that a class member who pays at Hartman's ASP has not been impacted; he would address the question of injury during the allocation phase, after a determination of liability. (Hartman Dep. Tr. 515.) Indeed, even an omniscient class member would be injured under Hartman's methodology: "if God were running one of these third-party payers and knew everything, then he would be impacted by it. He is still facing a fraudulently concealed AWP . . . ." (*Id.* at 103.)

Hartman's methodology is thus hardwired to find class-wide causation, injury and liability, because it assumes away the very question it purports to address: whether the impact of the alleged scheme can be determined without hearing testimony from individual class members concerning their expectations regarding the difference between actual or average sales prices and AWP.

2. The only way to correct this flaw is through individualized inquiry.

The only way to correct the errors that will result from using Hartman's "average" class-wide expectation would be through individual inquiries to determine each class member's real expectations. When Hartman was confronted with the deposition of a class member who testified that he did not believe that AWP had any consistent relationship to ASP, Hartman responded that he would want to ask more questions to understand this class member's testimony

[10] Hartman Dep. Tr. 371.

[11] Hartman Dep. Tr. 305-07.

(Hartman Dep. Tr. 366-67), and he conceded that, as a general proposition, actual information in specific cases trumps assumptions (*id.* at 205).[12]

Hartman's candid admissions that he would like to explore the individual expectations of each class member are completely inconsistent with a methodology that assumes that individual expectations can be ascertained by averages. And it is no answer that Hartman's average "yardstick" will be derived through surveys of real class members. The whole purpose of Hartman's survey is to question third party payers about their individual "expectations." (Hartman Dep. Tr. 348-49.) Averages are simply a way of ignoring the variations that will inevitably emerge from the survey, and of disregarding variations that will undoubtedly exist outside the surveyed group.

Because Hartman's methodology depends on uniform average "yardsticks," Hartman is compelled to ignore important contrary evidence of putative class members' actual, real world expectations. For example, when Hartman was confronted with a 1996 *Barron's* article that described spreads of 60% to 90% below AWP, he testified that this did not change his view that the appropriate "yardstick" for that time period is 10-20%. (Hartman Dep. Tr. 196-99.)[13] The reason: he assumed that the information in the article was not "pervasive enough or diffused enough" to affect expectations. (*Id.* at 200.) Hartman defended this assumption by further assuming that if class members had seen and understood the *Barron's* article, they would have been able to negotiate discounts of 60-90% below AWP that were in line with the article,

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[12] When confronted with this class member's testimony that he was not defrauded, Hartman dodged the question by saying he would want to look at the rest of the deposition to understand this testimony. (Hartman Dep. Tr. 231-32; *see also id.* at 95-96.) Similarly, when confronted with another class member's testimony that using a benchmark other than AWP would not make any difference in what class members pay for drugs, Hartman testified that he needed to read the deposition in order to understand the context. (*Id.* at 422; *see also id.* at 424.)

[13] This article is cited in the Amended Master Consolidated Complaint ¶¶ 319, 425.

because the actual contracts are "a measure of [class members'] revealed bargaining power and their revealed understanding." (*Id.* at 199, 201.) These serial assumptions illustrate precisely why an individualized inquiry is necessary. Hartman may be right or he may be wrong that not a single putative class member's expectations were influenced by the *Barrons* article or by any of the myriad government reports and other publications that described the pricing spread. But the only way to find what each purchaser knew is to ask, and that can only be done through individualized inquiry.

3. Hartman cannot postpone individualized inquiries by waiting to finalize his "yardsticks" until the damages phase.

Although Hartman's methodology calls for proving causation, injury and liability using average expectation "yardsticks," Hartman testified that he does not plan to finalize those liability/injury "yardsticks" *until the damages phase*:

> final yardstick spreads to be used to determine injury and damages during the Damages Phase of this Litigation would take these yardstick estimates as points of departure and refine them further through 30.b.6 depositions regarding the data provided by [defendants] and through depositions of appropriate personnel in TPPs and managed care organizations. *Such further refinement will more precisely determine expectations concerning a non-fraudulent relationship between AWP and ASP.*

(Hartman Decl. ¶ 29.)[14] The "non-fraudulent relationship between AWP and ASP" that Hartman refers to is his "but-for" spread – the basis of class-wide causation, injury and liability in his model. Thus, Hartman begs a critical question: how will he determine class-wide liability using expectation "yardsticks" that won't be finalized until after liability has been established?

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[14] *See also* Hartman Decl. ¶ 29 ("Sufficient information currently exists *and/or can be gathered during the Damage Phase of the Litigation* to calculate the yardstick (or but-for) spreads") (emphasis added).

Hartman's answer, revealed in his plan for the "damages phase," is to postpone the individualized inquiries that are necessary to prove liability. During the "damages phase" Hartman plans to depose class members in order to determine their "expectations concerning a non-fraudulent relationship between AWP and ASP." Individual inquiries through depositions figure prominently in Hartman's proposed "damages phase":

> I will designate depositions for a variety of persons responsible for pricing and purchasing decisions and reimbursement decisions regarding drug products during the Class Period. *The depositions will be aimed at clarifying the expectations of those persons in the industry who used AWP as a signal for underlying drug prices and costs* (ASPs and AACs).

(Hartman Decl. ¶ 39, emphasis added.)[15]

It is apparent that what Hartman refers to as the "damages phase" will not simply deal with quantifying damages. It will involve individual adjudications of *liability* for each class member. Hartman cannot determine whether a class member was defrauded until he finds out what the class member actually expected the spread between AWP and his ASP to be. And Hartman can't find *that* out without asking each class member about those expectations, which he plans to do in depositions at the "damages phase." This is further proof that Hartman's methodology is not capable of determining liability on a class-wide basis.

B. Hartman Calculates His "ASP" Baseline In A Manner That Is Unreliable and Inconsistent With The Testimony Of Plaintiffs' Own Pharmaceutical Industry Expert.

At the core of Hartman's analysis is a number he calls "Average Sale Price," or "ASP" (which he sometimes calls "actual/average acquisition cost" or "ACC"). Hartman's "ASP"

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[15] At his deposition, Hartman explained that, even if someone has not been misled, he would still assume "impact" because the mere fact that AWP is manipulated impacts every transaction that is subject to AWP. (Hartman Dep. Tr. 101-03, 437.)

purportedly represents the average amount that providers paid for a drug. Hartman uses "ASP" as the baseline for calculating (1) the so-called "actual spreads" between what the provider paid and the drug's AWP and (2) the so-called "but-for spreads" that would have existed in the absence of the alleged fraud. According to Hartman's methodology, there is liability if the "actual spread" is greater than the "but-for spread." But Hartman's entire methodology falls apart because his way of ascertaining his baseline "ASP's" is subjective, illogical and inconsistent with the opinions of Stephen Schondelmeyer, plaintiffs' own pharmaceutical industry expert.

Schondelmeyer stresses that "an accurate approach to estimating actual acquisition costs *must take into account the class of trade pricing practices of drug firms*." (Declaration of Stephen W. Schondelmeyer, sworn to September 2, 2004 ("Schondelmeyer Decl."), ¶ 88 (emphasis added).). He recognizes that there are different pricing, discounting and reimbursement practices that apply to (for example) retail pharmacies, hospitals and government purchasers. (*Id.* ¶¶ 86-88.) Hartman, however, ignores these critical distinctions. His ASPs lump together and average pricing information from multiple classes of trade. He then applies his multi-market ASPs to transactions involving only a *single* customer class. (*Compare* Hartman Dep. Tr. 121-22, 125-26, 610-611 *with* Hartman Decl. ¶ 33.). Hartman's ASPs therefore combine pricing information from markets that generally enjoy substantial discounts and are not even part of the case (*e.g.,* the inpatient hospital market) with pricing information from markets where discounting is often less significant (*e.g.,* the retail pharmacy market). (Hartman Dep. Tr. 126-27; 143, 272.) This approach renders his ASPs irrelevant to plaintiffs' claims. By including in his ASPs sales from irrelevant classes of trade that enjoy steeper

discounts than the plaintiff class, Hartman's methodology lowers ASPs and therefore increases his resulting "spread" calculations and liability/damages determinations.[16]

Second, in addition to ignoring the net *level* of list price reductions, Hartman also ignores the critical question of *what entity receives* the rebates. When the *provider* (*e.g.,* a retail pharmacist) receives a rebate from a drug manufacturer, then the "actual spread" between the provider's actual acquisition cost and AWP-based reimbursements would increase (all other things being equal). But if a *third-party payor class member* receives a rebate from a drug manufacturer, the net payment amount *decreases*, and the amount of the "actual spread" in the real world therefore actually *decreases* as well.[17]

A simple example illustrates the point: Assume a retail pharmacy normally pays $100 up front and that the AWP-based reimbursement paid by an insurer is $125. If the retail pharmacist normally also gets a $20 rebate from the manufacturer, Hartman's ASP would be $80 ($100 - $20), and the "spread" would be AWP minus ASP ($125-$80), or $45. By contrast, in the real world (but not in Hartman's), if such a $20 rebate goes to the third-party payor class member instead of the retail pharmacist, the ASP should still be $100 but the class member's net payment would decrease to $105 ($125 minus the $20 rebate). The resulting "real world" spread would

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[16] At his deposition, Hartman was unable to explain the inconsistency between his approach and Schondelmeyer's, other than to suggest that Schondelmeyer's approach did not relate to any "model" for the case. (Hartman Dep. Tr. 138-39, 146.) But Schondelmeyer's believes that recognizing the differences among classes of trade is one of the "key dimensions" in establishing "the feasibility of retrospective determination of class injury and a methodology to determine class wide damages." (Schondelmeyer Decl. ¶ 85.) Schondelmeyer made the same point in a paper that Hartman relied upon in his declaration. (Hartman Decl. Attach. B at 6.)

[17] Such rebates can go either directly to an insurer/reimburser or can be passed onto the insurer/reimburser through a PBM. One 2000 government study estimated that PBMs pass on to their insurer customers about 70 to 90 percent of the rebates they receive from manufacturers. U.S. Department of Health and Human Services, "Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices at Chapter 3, available at http://www.aspe.hhs.gov/health/reports/drugstudy/chap03.htm.

then only be $5 – the difference between the net reimbursement and retail pharmacist's acquisition cost. But when Hartman's methodology is applied to the above example, even if the rebate goes (directly or indirectly) to the third-party payor class member, the ASP would still be $80 (even though the retail pharmacist actually paid $100) and the "spread" would still be $45 – *even though the reimburser would actually only pay $5 more than the retail pharmacist paid.* Thus, in the real world, who gets the rebate makes a great difference, but Hartman ignores that distinction.

By ignoring these two critical distinctions – class of trade and "who gets the rebate" – Hartman's methodology causes him to conclude that "actual spreads" are greater than they really are. By ignoring (1) key differences in class of trade pricing practices (thereby contradicting plaintiffs' other expert), and (2) the obvious real-world difference caused when manufacturer rebates go to providers versus when they go to reimbursers, Hartman skews his ASPs downward and his actual spreads upward. Because ASPs are Hartman's baseline for calculating the actual spreads he uses to determine whether there is liability, these fundamental defects render Hartman's entire methodology unreliable.

C. Hartman's Methodology Fails To Account For The Trade-Offs Between Drug Price And Other Contract Terms That Are Reflected In Drug Purchase Contracts.

Hartman's use of class-wide "averages" also causes his methodology to miss the trade-offs among the terms and conditions that third-party payors separately negotiated with PBMs. Drug purchase contracts are not uniform. They reflect trade-offs among many different factors such as price, rebates, dispensing fees, clinical service fees, transition fees and administrative

fees in PBM contracts. (Hartman Dep. Tr. 290-92.)[18] The result is that "the differentiation of the products and the bundles of services that are offered priced by service differ, and the contracts are very complex." (*Id.* at 480.) Similarly, contracts between payers and providers for physician-administered drugs often bundle the price of the prescription drug together with the cost of administering that drug. In this way pricing permits payers to subsidize the cost of services through prescription drug costs. Because of variations in negotiating power in both the self-administered and physician-administered markets, how these trade-offs are implemented will vary from contract to contract. Hartman admits that there will be differential abilities of different entities in negotiations and there will be differential results related to discounts paid that might be reflected for different branded drugs of different therapeutic capabilities." (*Id.* at 599-600.)

Hartman admits that his methodology does not consider these trade-offs or differences when determining whether a class member has been injured. (Hartman Dep. Tr. 290-92.) Rather, his methodology assumes that in the "but-for" world, the only thing that would change is the benchmark from which the discount off of AWP is calculated – because that is what he has been asked to do by plaintiffs' counsel. (*Id.* at 295-97.) Yet a whole host of contract-specific trade-offs that affect net price can only be determined through individualized inquiry and proof, not class-wide averages.

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[18] For example, Hartman concedes that if the price for the ingredient cost goes down, the dispensing fee could go up. (Hartman Dep. Tr. 298.)

D. Hartman's Plan To Develop Class-Wide "But-For" Spreads By Asking A Few Putative Class Members Today What Their Expectations Were Prior To 1991 Is Facially Unreliable.

Hartman's "but-for" spreads are supposed to reflect class members' expectations concerning the size of the spread in the absence of the alleged scheme. Because plaintiffs allege an industry-wide fraud from 1991 until the present, Hartman proposes to go back to the period prior to 1991 in order to estimate class members' expectations when "untainted" by the alleged scheme. (Hartman Decl. ¶¶ 21, 39; Hartman Dep. Tr. 213-17.)

This approach is flawed as a matter of statistical science as we show in Section III below. But as a matter of common sense, there can be no assurance that survey respondents will accurately recall their "expectations" from fifteen years ago. Furthermore, responses in 2004 or 2005 are likely to be influenced by information that respondents learned over the last decade-and-a-half and biased by the prospect of a financial recovery. On its face, Hartman's survey plan cannot be relied upon to generate reliable "yardsticks" or "but-for" spreads.[19]

III. Hartman's Methodology Lacks All Of The Indicia Of Reliability Identified In *Daubert*.

Because of the fundamental flaws identified above, Hartman's "expectation" methodology cannot pass muster under *Daubert*. "Federal Rule of Evidence 702 'assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.'" *Cipollone v. Yale Indus. Prods., Inc.*, 202 F.3d 376, 380 (1st Cir. 2000) (quoting *Daubert*, 509 U.S. at 597). Among other things, the Rule directs district judges to ensure that proffered expert testimony "is the product of reliable principles and

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[19] Hartman suggests that he may be able to develop his "but-for" spreads in part by looking at drugs that were unaffected by the alleged scheme. But Hartman has not identified a single drug that he believes was unaffected by the alleged industry-wide scheme that could help him develop his "but-for" spreads. (Hartman Decl. ¶ 21; Hartman Dep. Tr. 177.)

methods." Fed. R. Evid. 702. "[T]he trial court must decide whether the proposed testimony, including the *methodology* employed by the witness in arriving at the proffered opinion, 'rests on a *reliable foundation* and is *relevant* to the facts of the case.'" *Ed Peters Jewelry Co. v. C. & J. Jewelry Co.*, 124 F.3d 252, 259-60 (1st Cir. 1997) (citing *Daubert*, 509 U.S. at 597) (expert testimony that was "internally inconsistent and unreliable" excluded) (emphasis in the original).

Courts typically consider several factors when assessing the reliability of proffered expert testimony. These factors, which are derived from *Daubert*, include:

> (1) whether the opinion can be or has been tested; (2) whether the theory or technique on which the opinion is based has been subjected to peer review and publication; (3) the technique's known or potential error rate; (4) the existence and maintenance of standards controlling the technique's operations; and (5) "general acceptance."

Sutera v. Perrier Group of America, Inc., 986 F. Supp. 655, 661 (D. Mass. 1997); *United States v. Sampson*, ___ F. Supp. 2d ___, 2004 WL 1906872 at *45 (D. Mass. Aug. 26, 2004) (identifying the five *Daubert* factors).

As explained below and in the attached declaration of Dr. Halbert L. White ("White Decl."), Hartman's methodology lacks all of these traditional hallmarks of scientific reliability.

A. Hartman's Methodology Cannot Be Tested.

Hartman does not deny that he created his "expectation" methodology specifically for this litigation (Hartman Dep. Tr. 54-55.) Thus, it has never been tested. Indeed, as Dr. White explains, Hartman's methodology is *impossible* to test because it is based on a tautology that assumes the answer it purports to analyze. (White Decl. ¶¶ 10-11.) Dr. White concludes that Hartman's "expectation" methodology accordingly "violates accepted principles of science":

> A tautology can never be scientific because science requires hypotheses that can be proven untrue. . . . By assuming the conclusion he purports to investigate, Dr. Hartman's method offers

> no testable predictions that can be falsified and no meaningful ways exist to evaluate the validity of the method.

(*Id.* ¶ 12.) "By applying a tautology to the question of whether all or substantially all payors overpaid for prescription drugs, Dr. Hartman has failed to perform a meaningful analysis." (*Id.* ¶ 14.)

B. Hartman's Methodology Has Never Been Published or Subjected To Peer Review, Nor Is It Generally Accepted Within The Field.

Hartman does not claim that his created-for-litigation "expectation" methodology has been subjected to peer review. Dr. White is the editor of the Cambridge University Press journal, *Abstracts of Working Papers in Economics,* and he has served on the editorial boards of several other professional journals. (White Decl. ¶ 4.) Because Hartman's methodology employs a "flawed survey methodology" which has "no foundation in the economic or statistical literature" (*id.* ¶ 19) and his "tautological methodology violates accepted principles of science" (*id.* ¶ 12), Dr. White concludes that Hartman's "expectation" methodology "would never be published in a peer-reviewed journal." (*Id.* ¶ 13.) Similarly, Hartman's "expectation" methodology "would never . . . be accepted within the community of economists." (*Id.*)

C. Hartman's Methodology Has No Known Or Potential Error Rate.

Because Hartman's "expectation" methodology is untestable (¶ 12), it is not possible to determine its error rate. Furthermore, Hartman's plan to survey class members today about their expectations over a class period that extends back to 1991 is statistically unsound. Hartman's survey methodology depends on gathering "ex post information about ex ante beliefs," but "[a]cademic research reveals significant biases and an unknown error rate in estimating beliefs in this way." (*Id.* ¶ 22.) Moreover, Hartman's assumption that "but-for" expectations would have remained exactly the same from 1991 until the present is not reliable: "despite the evidence that payor expectations adjust, Hartman proposes to use yardsticks based on information 'prior to the

alleged fraud' to proxy for beliefs during the class period, thereby ignoring this adjustment." (*Id.*) "The economic and statistical professions would not accept this methodology." (*Id.*)

D. There Are No Standards To Control The Operation Of The Methodology.

By constructing a methodology around a tautology, Hartman insulates his calculations from the objective standards that govern methodologies based on the scientific method. A prominent example is Hartman's use of averages and "yardsticks" as a proxy for class members' varied, real-world expectations. As Dr. White testifies, "average payor injury conveys no information about individual injury," because "as long as Dr. Hartman's average yardsticks indicate injury, they will attribute injury to all putative class members whether or not they were individually overcharged for prescription drugs." (White Decl. ¶ 17.) Moreover, by assuming what it sets out to prove, Hartman's methodology by definition excludes the possibility that causation, injury and damages might not be class-wide. (*Id.* ¶¶ 17-18.) This disregards the fundamental scientific tenet that "[r]eliable application of scientific method requires consideration of relevant factors that might disprove Dr. Hartman's hypothesis." (*Id.* ¶ 20.)

CONCLUSION

For the reasons set forth above, Dr. Hartman's declaration should be stricken.

Respectfully submitted,

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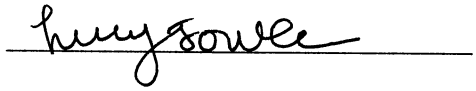
Dated: October 25, 2004

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by express mail on October 25, 2004.



CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2004, I caused a true and correct copy of the Track 1 Defendants' Memorandum in Support of Motion to Strike the Declaration of Raymond S. Hartman to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

/s/
Jason R. Litow